How to protect consumers against the risks posed by the online pharmacy market

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Abstract

Background: Regulation of the online pharmacy market is minimal. Attempts have been made to provide a framework but neither well-established hard laws nor soft laws exist in order to protect the consumer and the regular market from the risks posed by the online pharmacies.

Objective: The objective of this research is to analyse how the online pharmacy market can be regulated in order to protect the consumer against the risks of ordering medication online. The question to be answered is thus: How should the online pharmacy market be regulated in order to diminish to the fullest extent possible of the risks faced by consumers when ordering medication online?

Methods: In order to answer the research question, the risks of online pharmacies were identified first. Then, a comparative analysis of existing and evolving law in several (western) states was conducted. In addition, other initiatives, such as certification and accreditation methods were analysed.

Results: For now, the expected outcome of the research will be that a combination of hard and soft law may be the most profitable one. State regulation should provide a clear legal framework imposing the legal boundaries, while verification mechanisms should provide assistance and give guidance to the online pharmacies in their quest for a reliable, trustworthy market share. In addition, it is of importance to harmonise the approach between states towards the regulation of online pharmacies as much as possible in order to provide a common framework for everyone, diminishing the issues arising from cross-border trade.

Keywords: Health Internet; Pharmacy online; Quality; Ethics, Trust

Introduction

The percentage of people going online is constantly growing. According to the Internet World statistics, in December 2011, nearly 2.3 billion people, or 32.7% of the world's population, were using the Internet [1]. In Europe 61.3% of the population is using the Internet. In Switzerland, more than 8 out of 10 have Internet access. The number of persons using the Internet to search for health information is still increasing exponentially. In 2010, one Swiss citizen out of two was using the Internet to find health information [2]. According to the study mandated by Swisscom, this number has risen to 84% of the respondents [3]. The information that were most searched for were related to symptoms, diseases and possible treatments [3]. More and more sites offer online pharmacy services on the Internet. ‘Online pharmacy’ is defined as ‘a person, entity or Internet site that knowingly or intentionally (attempts to) delivers, distributes, or dispenses, a controlled substance by means of the Internet’ (exceptions to this definition are not discussed here).

Even though the services provided by online pharmacies are convenient and their product pricing can be more attractive than at a pharmacy store [4], the regulation of online pharmacies is still in development and evolving. Several problems have been identified, related to the upcoming online pharmacy business. Main issues are the health risks and that the number of falsified medications on the market increases and continues to increase due to the possibility of ordering medication online from all over the world. In Europe, the most important counterfeiters are drugs at 32%, followed by furniture (30%) and bags (17%) [5]. Another issue is the lack of control in ensuring whether the websites hosting online pharmacies are real, licensed pharmacies or whether they are deceptive pharmacies.

Regulation of the online pharmacy market is minimal. Attempts have been made to provide a framework but neither well-established hard law nor soft law exists in order to protect the consumer and the regular market from the risks posed by the online pharmacies. Knowing that the Web has no frontier, the online pharmacies usage has no limit even in countries where this usage is prohibited, like Switzerland or France. In Switzerland, customs have sent 1298 suspicious shipments to Swissmedic, and from these 1132 administrative procedures have been opened. They were able to identify 33 sources of illegal drugs online providers abroad. The main drugs seized by the Swiss customs were erectile drugs, performance enhancing drugs, diet products, sleeping pills and tranquillisers, psychotropic, lighting or browning skin products [6]. This range of products touches the concerns of a wide population, and potentially more and more people will be able to buy such products online. These products have been analysed by Swissmedic. A total of 90% have been the subject of a legal administrative procedure. Swissmedic has forced 21 illegal online pharmacies websites to close in Switzerland [7]. It is important to note that customs only detect fraudulent products while doing random checks, so
the number mentioned above could be the tip of the iceberg.
The objective of this research is to understand from the current regulations and civil societies’ actions what procedures need to be taken at an international level in order to make the Internet citizen more aware of the reality, risks and consequences on ordering drugs online. As an organisation dedicated to guide the citizen towards reliable and trustworthy online health information, the Health On the Net Foundation is concerned with the online pharmacies topic.
1. For the purposes of this article a slightly adapted version of the definition of the ‘online pharmacy’ is proposed. 21 U.S.C. 802 (52) http://definitionsuslegal.com/o/online-pharmacy/
2. Swissmedic : www.swissmedic.ch Swiss institute for therapeutic products

Methodology

In order to answer the research question, the risks of online pharmacies were identified first. Then, a comparative analysis of existing and evolving law in several (western) states was conducted. In addition, other initiatives, such as certification and accreditation methods were explored. After having set out the advantages and disadvantages of the hard and soft law approaches, recommendations will be given as to how to proceed with regulating the online pharmacy market in order to diminish, to the fullest extent possible, the risks faced by consumers when ordering medication online.

What are the risks posed by online pharmacies?

1.1 General risks

The main direct dangers include health risks, in some cases life threatening [8]. A study conducted on drugs for the treatment of erectile dysfunctions from seizures by Italian police forces or bought from illegal online pharmacies showed that in “19% of the samples a potential health risk for patients was identified due to either the presence in the sample of more than one undeclared PDE5(s) or an amount of the active ingredient higher than that declared (up to 190% of the maximum dose) or to the presence of potentially dangerous excipients of non-pharmaceutical origin or quality (e.g., gypsum or non-purified talc)” [9].

Online pharmacies contribute in “increasing use of prescription controlled substances by adolescents and others for nonmedical purposes, which has been exacerbated by drug trafficking on the Internet.” The U.S. Congress passed the Ryan Haight Act precisely for this reason [10-11].

The rise of online pharmacies and their popularity is causing a major increase in the counterfeit drug movement and facilitates the inclusion of counterfeit medication in the supply chain [12]. A study on the medicines for the treatment of erectile dysfunctions revealed “that 24% of the analysed samples were counterfeit and 54% were illegal medicines. In 12% of the cases an intermediate classification (illegal/counterfeit) was assigned. Only 7% of the samples were original [9].”

The Internet does not have borders. Therefore, consumers can order medication via online pharmacies from anywhere in the world. This increases the risk and the urgency to globally act.

1.2 Risks due to non-transparent information

Online pharmacies do not always provide transparent, complete, quality information leaving consumers at the risk of receiving information which is not trustworthy. A few points will be mentioned here shortly [13]. No information is provided about the identification and qualification of the medical professionals who check the prescription, resulting in consumers having no idea who actually checks and fills their prescription.

- Online pharmacies do not always request a prescription. A prescription requirement should be present because people are not always skilled enough to make their own choice. In some cases, online questionnaires substitute the lack of prescription. However, this is not at all times sufficient due to reasons such as incompleteness of the questionnaires or a lack of patient-physician relationship.

- Often no or poor information is provided about the privacy policy of the website: it is not explained what is done with the personal and medical information given by the consumer, who has access to this information, how long it is stored, what is being done with the information and so on.

- Actualisation of stock is not provided on the website: for example when a medication has been taken out of the market and the online pharmacy still provides the medication.

Risks due to lack of awareness

- Many college-educated people cannot see the signs of danger displayed by rogue Internet pharmacies, which means that for the consumer it is difficult to distinguish good online pharmacies from rogue online pharmacies [14].

- Consumers are not sufficiently informed about the risks of purchasing medication online. No means is provided in order to identify trustworthy online pharmacies.

An overview on online pharmacies regulation

In some countries special regulation has been put in place, whereas in other countries the online pharmacies are prohibited. This section gives an overview on the solutions adopted by different countries.

1.3 United States regulation

The United States have a specific regulation with regard to online pharmacies which is called the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, amending the Controlled Substances Act to address online pharmacies [11]. Prescription drugs may be delivered, distributed or dispensed by means of the Internet only under the a certain number of conditions such as a valid prescription for controlled substances dispensed being necessary by a practitioner who has conducted at least 1 in –person medical evaluation of the patient or by a covering practitioner. The online pharmacy should be backed-up by a pharmacy re-
registered with the pharmacy’s drug Enforcement Administration and a certification that the pharmacy is registered to deliver, distribute or dispense by means of the Internet controlled substances should be accessible from the homepage. A statement should also be provided on the homepage that the online pharmacy complies with the requirements as laid down under the Ryan Haight Act to comply with the state law [11].

1.4 European Union
The EU adopted a new directive to protect consumers against the rising threat of falsified medicines, which is partly due to the rise of online pharmacies. A margin of appreciation is left to the member states implementing the directive. Another important point in the directive is that a European logo should be developed in order for consumers to easily recognise approved websites operating legally, with a link to the national registration office. The EU member states take different positions on online pharmacies. France does not allow the sale of prescription drugs via the Internet. There is no explicit law prohibiting the sales but a combination of several laws prevents online pharmacies to be established in France. The Netherlands does not prohibit the online sales of prescription drugs, as long as several conditions have been fulfilled, such as that the prescription has to be written by a physician who has seen the patient at least once and that the pharmacist is registered [15]. The product information should be balanced, complete and objective in order to avoid advertising of medicinal products and should not lead to advertising of prescription drugs to consumer [16]. Germany modified its legislation in 2008 allowing online pharmacies under certain conditions [17]. The UK has more or less the same legislative requirements as in the Netherlands.

1.5 Switzerland
In Switzerland the sales of medicinal products via the Internet is in principle prohibited, but the cantons can allow the sales under certain conditions [18]. One of the conditions is the necessity of a prescription.

1.6 Canada
In Canada only brick-and-mortar pharmacies are allowed to operate online pharmacies. Pharmacies in Canada are regulated by the provinces. To operate a pharmacy in Canada, the premises must be licensed by the provincial pharmacy board, managed by a licensed pharmacist, and meet stringent standards for the storage and disbursement of medication [19-20].

Initiatives by associations, agencies and authorities
In addition to the regulations, initiatives have been taken, such as verification programmes, guidelines and certification mechanisms, by non-governmental bodies to give guidance in the establishment, development, verification and safety of online pharmacies.

1.7 United States and Canada
The National Association of Boards of Pharmacy (NABP), with board members from US states, New Zealand, the District of Columbia, Guam, Puerto Rico, the Virgin Islands and 8 Canadian provinces, has developed the Verified Internet Pharmacy Practice Sites (VIPPS) programme. For a pharmacy to be VIPPS accredited, ‘a pharmacy must comply with the licensing and inspection requirements of their state and each state to which they dispense pharmaceuticals. In addition, pharmacies displaying the VIPPS seal have demonstrated to NABP compliance with VIPPS criteria including patient rights to privacy, authentication and security of prescription orders, adherence to a recognised quality assurance policy, and provision of meaningful consultation between patients and pharmacists.’ [21]
It is a voluntary programme and at present 32 pharmacies in the US have been accredited which can be distinguished by a logo of VIPPS on their website, while none of the Canadian online pharmacies has been accredited.

1.8 Switzerland
In Switzerland the agency for the authorisation and supervision of therapeutic products, Swissmedic, has issued a guide about the sales of medication over the Internet [22]. The guide specifies which points to check when looking for pharmacies online. Examples they give are to check who is responsible for the website and if the website provides complete and actual information.

1.9 Netherlands
In the Netherlands, the branch organisation of pharmacists ‘Koninklijke Nederlandsche Maatschappij ter bevordering der Pharmacie’ (KNMP) issued a guideline ‘Online Pharmaceutical Care and Service Provision’ providing recommendations to pharmacies about how to conduct quality care and service via the Internet complementing the regular guidelines for pharmacies [23].

1.10 United Kingdom
In the UK there is the possibility to place a logo on the website when the pharmacy has been registered under the General Pharmaceutical Council which is obligatory for all existing pharmacies in the UK [24]. In this way legitimate pharmacies can be distinguished from others. No specific guidelines applicable to online pharmacies have been developed. However, some guidelines can be deduced from general guidelines applicable to pharmacies.

1.11 Certification

1.11.1 Legitscript
Legitscript certifies online pharmacies domiciled in the US. This is based on eleven standards with which the online pharmacy should comply. Requirements are, for example, that the pharmacy is licensed, registered with the US DEA (DEA Drug Enforcement Administration), has had no significant recent disciplinary sanctions, domiciled in the US, has a valid prescription, complies with all provisions of federal and state law, respects the privacy and complies with the relevant regulation, provides patients with good services with an accurate, readily accessible and responsive phone number, guarantees website transparency, has trans-
parent information on the domain name registration, and affiliated websites should respect the same standards as the site [25]. The public can report suspicious online pharmacies.

1.11.2 HONcode

The Health On the Net Foundation has developed a code of conduct (HONcode) providing certification for websites worldwide containing medical or health information [http://www.healthonnet.org/]. Some online pharmacies have been certified by the Health On the Net Foundation but at the moment the certification of online pharmacies has been suspended until a harmonised approach can be taken with regard to online pharmacies on an international scale. Only US and Canadian online pharmacies which have been verified by the VIPPS programme and legistscript are eligible. The certification of the Health On the Net Foundation is based on 8 ethical principles, focusing on trustworthy and transparent information provision of the health website. Amongst others, the website should provide objective and balanced information, provide information about the identification and qualifications of the responsible people, editors and authors of the website, information should be dated and referenced, and funding sources should be identified. Regular review is conducted and a complaint system is open to the public.

3 http://www.nabh.net/programs/accreditation/vipps/find-a-vipps-online-pharmacy/ 4 http://www.napra.org/pages/Practice_Resources/find_a_vipps_certified_pharmacy.aspx

Discussions and Conclusions

In general, the risks of online pharmacies are addressed through hard and soft law approaches. The problem is that the legislation is fragmented and mostly not specifically aimed at online pharmacies but that several different parts of the legislation address the online pharmacy market, such as legislation concerning advertising, medicinal products, privacy issues, IT and so on. At the same time, guidelines, certification and verification mechanisms are in place but they all cover different aspects of the online sales of medication. In almost every state the rules differ, while at the same time the Internet facilitates the sales of medication from all over the world not taking into account the limits of the law.

Therefore, it is highly recommended to develop and adopt one specific standardised code of conduct for online pharmacies, harmonising the approach towards online pharmacies as much as possible, while keeping the market open and protecting consumers at the same time. This code of conduct should be international and should contain the minimum requirements which can be applicable to all the different legal systems. It should also contain a part on the quality of information provided on the websites of the online pharmacies. Most of the discussed verification and certification mechanisms, some states and also the EU use a seal to identify which online pharmacies are in compliance with the requirements necessary, which would also be recommendable for the standardised code of conduct. Furthermore, it has to be possible to enforce the code of conduct.

To develop such a code of conduct, cooperation is needed at horizontal and vertical levels, including all important players in the field. At the same time, launching such a code needs to be highly promoted among consumers, making them aware which information can be trusted and which information has not been verified.

This will lead to reducing the risks posed by online pharmacies even more, having a harmonised approach so that there are fewer possibilities to have counterfeit and falsified medication being sold via rogue online pharmacies because it will be more difficult for them to enter the market. At the same time, the minimum requirements will set the standard for the provision of quality information on the website of the online pharmacies, while making the public aware about what can be trusted and what can not.

The user has no global access to a trustworthy repository which regroups all the certified online pharmacy worldwide and is not aware of the existence of a certification scheme. All the initiatives should be federated in order to explain their role and give access to the certified or evaluated online pharmacies.

In general, the public awareness should be raised as much as possible. This will mostly be up to the governments to undertake action. At the same time, guidelines, verification and certification mechanisms can underline the necessity of information to the public about the risks of ordering medication online.

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